

d.) **Remarks**

The specification and claims 1, 13, 41 and 42 have been amended. The specification was amended to claim priority properly to co-pending U.S. Application No. 10/020,923. The claim amendments are minor wording changes requested by the examiner to clarify the claimed invention. Support for these amendments can be found in the specification and the existing claims. Claims 1-44 are pending.

**Remarks Regarding 35 U.S.C. § 112, Second Paragraph**

Claims 1-25 and 36-39 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

(a) It is alleged that claim 1 is unclear because what the reporter molecule is conjugated to and how to interpret “conjugated to a reporter molecule to the digested bacteria.” Further, claim 1 is alleged to be unclear for reciting “adding a primary antibody specific to said marker to the digested bacteria.” Applicant respectfully disagrees; however, claim 1 has been amended to clarify that primary antibody, which is specific to said marker, is added to the digested bacteria; and second antibody, which is specific for said primary antibody and also conjugated to a reporter molecule, is also added to the digested bacteria. Accordingly, it is believe that the examiner’s concerns are now moot.

(b) It is alleged that claims 1 and 13 are unclear in that they do not require contact between the primary antibody and the unidentified marker. Further, it is allegedly also unclear where the antibodies are being added. Further still, it is alleged to be unclear how bacteria typing can occur. Applicant respectfully disagrees.

First, applicant respectfully notes that “contact” between the marker and the antibody occurs when antibody specific for the marker and the marker are placed together. Nevertheless, claim 1 has been amended to indicate that contact results from placing antibody with marker and secondary antibody with primary antibody, and this of aspect of the rejection is moot.

Second, claim 1 also recites that primary and secondary antibodies are each added to the digested bacteria. Withdrawal of this aspect of the rejection is respectfully requested.

Finally, it is believed clear to those skilled in the art upon reading the specification and the claims that the claimed method can be practiced with bacteria-specific or bacteria-non-specific antibodies. Thus, one performing the method can identify and quantify most any microorganisms present in a sample. This is discussed both generally and specifically in the specification such as, for example, at page 8, line 30 to page 9, line 2; and also at page 10, lines 1-6, lines 12-18, and lines 23-25. Withdrawal of this aspect of the rejection is respectfully requested.

(c) With regard to claims 41-42, it is alleged to be unclear how a kit claim can contain a method step. Both claims have been amended and this rejection is moot. Withdrawal of this aspect of the rejection is respectfully requested.

(d) With regard to claims 1-25 and 36-39, it is alleged that these claims are incomplete because they lack essential contact steps and correlation steps that correlate the detected reporter molecule to determining the type or quantity of microorganisms. Applicant respectfully disagrees. However, as indicated above, these claims have been amended to more specifically clarify the specific contacts. Further, as discussed here, determining the type and quantity of microorganisms captured is clearly determinable by one skilled in the art from the selection of antibody and substrate (*e.g. see* specification page 8, line 30 to page 9, line 2; and page 10, lines 1-6, lines 12-18, and lines 23-25.). No more is required and withdrawal of this aspect of the rejection is respectfully requested.

Thus, the rejection of claims 1-25 and 36-39 under 35 U.S.C. § 112, second paragraph, is overcome or moot, and applicant respectfully requests that it be withdrawn.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

A. Claims 1-44 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

It is alleged that the specification does not provide support for immobilizing a capture antibody specific to one or more types of bacteria on a solid support. Further, applicant is requested to identify structural characteristics of an immobilized capture antibody specific to one or more types of bacteria. Applicant respectfully disagrees.

Applications are read and interpreted in light of the skill in the art. As is believed to be agreed by the examiner, the skill in the art of the claimed invention is very high and the creation and use of type-specific antibodies is routine.

The examiner alleges in the office action that this is a new matter rejection. However all words and ideas of these claims are fully supported in the specification. For example, the specification at page 8, line 30 to page 9, line 2, recites that primary antibodies of any available specificity can be used. Also clearly set forth in the specification is the idea that "typing" refers to the specific determination of the genus and/or species and/or serotype of the microorganism (see specification, page 10, lines 12-22). It is further clearly stated that microbes are typed by the ability of antibodies produced specifically to that microbe to capture the microorganism. No additional disclosure is required.

Further, the claimed invention is not directed to the creation of type-specific antibodies, but to new methods for typing and enumerating microorganisms. In these methods, antibodies are used, but the creation and use of any particular antibody is well within the knowledge and skill of one of ordinary skill. Accordingly, no further disclosure in the specification can be required.

Thus, the rejection of claims 1-44, under 35 U.S.C. § 112, first paragraph, is overcome and applicant respectfully requests that it be withdrawn.

**B.** Claims 8, 25 and 29 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

It is alleged that the specification supports individual reporter molecules but not combinations of reporter molecules. Applicant respectfully disagrees.

Reporter molecules are chemicals that are very well known to those of ordinary skill in the art. In fact, reporter molecules have been known and used individually and in combination in association with antibodies, and specifically with detection methodology, for decades. Thus, combinations of reporter molecules are very well known by those skilled in the art and very well known in the specific field of the claimed invention. To require applicant to include a discussion that multiple reporter molecules can be used in detection methodology is superfluous and adds nothing not already well known to those skilled in the art. Applications are to be read and interpreted by those skilled in the art, and, accordingly, no further disclosure is necessary than already exists.

Applicant respectfully requests that the rejection of claims 1-35, under 35 U.S.C. § 112, first paragraph, be withdrawn.

**Remarks Regarding 35 U.S.C. § 102(b)**

Claims 1-44 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Thacker (WO 99/12015). The specification has been amended to indicate that the instant application is a continuation-in-part of co-pending U.S. Patent Application No. 10/020,923 entitled "Methods for the Rapid Detection of Actively Respiring Microorganisms," filed December 19, 2001, which is a Divisional Application of U.S. Patent Application No. 09/148,491 of the same title, which issued as Patent No. 6,344,332 on February 5, 2002, and claims priority to Provisional Application No. 60/057,657, filed September 5, 1997. U.S. Patent Application No. 09/148,491 is specifically incorporated by reference in the specification at page 18, lines 4-7, and all applications name as their sole inventor James D. Thacker and all applications are owned by applicant by assignment. An unexecuted Substitute Declaration is attached hereto and will be

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promptly filed upon receipt of the inventor's signature. Accordingly, WO 99/12015 can no longer be considered prior art and this rejection is moot.

### **Conclusion**

The application is in condition for examination and the prompt issuance of an Office Action is respectfully requested.

If the examiner has any further questions regarding this case, the undersigned would welcome an interview. Please feel free to contact the undersigned at the telephone number indicated.

If there are any fees due with the filing of this Response, including any fees for an extension of time, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952.

Respectfully submitted,  
Morrison & Foerster LLP

Date: August 23, 2004

By \_\_\_\_\_

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Enclosed: Unexecuted Substitute Declaration

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